

REMARKS

The **final** Official Action of mailed June 17, 2004, has been carefully reviewed. Upon entry of the amendment presented above, the claims in the present application will be claims 1-16, including newly presented independent claim 16 which combines features of claims 2, 3, 6 and 7. Applicant's claims define novel and unobvious subject matter under Sections 102 and 103 and should be allowed. Accordingly, applicant respectfully requests favorable reconsideration, entry of the amendment presented above, and allowance.

As indicated above, new independent claim 16 is proposed to be added, and incorporates features of claims 2, 3, 5 and 6. This claim is patentable for the same reason as the other claims, as pointed out below.

Claims 1-6 and 15 have been finally rejected under Section 103 as obvious from Woolridge in view of Stehlin, Kavanagh, Uhle and Zubkova. These claims have also been rejected as obvious under §103 from Stehlin, Kavanagh, Uhle and Zubkova in view of Woolridge.¹ These rejections are respectfully traversed.

¹ Applicant does not understand this rejection in the sense of which citation forms the basis for the rejection among Stehlin, Kavanagh, Uhle and Zubkova, and how that basic or primary reference is obviously modified by the other three references and then by Woolridge.

As understood, both rejections are based on combining bits and pieces from five different citations, all of which have been discussed to some extent in the preceding Office Action, the remarks of which are respectfully repeated by reference. Of the five citations, applicant understands that Woolridge is considered to be the most fundamental. Accordingly, applicant at this time focuses attention on Woolridge and particularly its deficiencies with respect to the present invention as noted below, and applicant notes that none of the other four citations have been cited to make up for the Woolridge deficiencies pointed out below, and presumably do not do so².

Thus, based on what is noted below as to the deficiencies of Woolridge, and the fact that the other citations have not been relied upon to make up for these deficiencies, it will follow that no combination of the five citations (even if obvious, not admitted) could reach the claimed subject matter.

Woolridge et al studied the question of whether or not a change in the composition of human milk affect sucking patterns and milk intake, and Woolbridge is a report on their results. For this purpose, the researchers simulated the

² Undersigned does not have copies of Stehlin, Kavanagh, Uhle or Zubkova, and so requests copies from the PTO.

model of fore-milk and hind-milk and fed infants with fat-modified breast milk in bottles, in three different ways:

- (1) a group of 8 infants were fed low fat-milk, i.e. fore milk, followed by high-fat milk, i.e. hind milk;
- (2) a group of 8 infants were fed low-fat followed by low fat-milk; and
- (3) a group of 8 infants were fed high-fat followed by low-fat milk.

Based on the intake volume of milk (Fig.1, page 1293) and the analysis of the sucking patterns of infants feeding on low-fat and high-fat milk (Fig. 2, page 1293), Woolridge et al concluded that changing the composition of milk did not affect the milk intake or the sucking patterns. In summary, Woolridge et al stated that "*switching the baby from low-fat breast milk to high-fat breast milk did not alter either milk intake rate or sucking patterns*" (last sentence of the DISCUSSION section of the publication).

What then does Woolridge teach the person of ordinary skill in the art? Woolridge teaches nothing which one of ordinary skill in the art can put to good use. Woolridge teaches that the tests conducted "did not alter either milk intake rate or sucking patterns". Why then would the person of ordinary skill in the art seek to adopt anything

taught by Woolridge when it had no positive effect? The Woolridge teachings are therefore a disincentive for "switching the baby from low-fat breast milk to high-fat breast milk"

Woolridge thus teaches away from the present invention. Woolridge does not provide the skilled worker with any teaching that would result in the invention of the present application. On the contrary, Woolridge provides the skilled artisan with the knowledge that infants stop feeding irrespective of what milk (low fat or high fat) they feed on, and irrespective of the sequence of feeding. Certainly, Woolridge does not suggest or teach the benefit of feeding infants with one particular milk combination of the combinations discussed in the publication.

Furthermore, Woolridge does not motivate the skilled artisan to combine any teaching therein with any teaching of any of the other publications applied in order to gain any specific benefit. Thus, the present invention cannot validly be said to have been obvious in view of Woolridge alone or in combination with the other citations; it would be impossible for a person skilled in the art, on the basis of Woolridge, to arrive at the present invention even if Woolridge were obviously combined with the other publications, which (as

understood) merely provide the skilled reader of those publications with the knowledge that simulated milk formulations may be prepared.

The Woolridge study suggests that the leading factor which determines when infants stop feeding is the volume of the intake and the increased effort put into sucking, and not the sequence of fore or hind milk feeding. In fact Woolridge does not even suggest that any such sequence of feeding may be necessary or even desirable. This means that it would be sufficient to feed the infant with a large enough volume of a low fat or a high fat formula or with a general formula, as is the case with currently available formulas. Such feeding would result in the termination of feeding irrespective of the nature of the formula, i.e. the fat content.

Further with respect to the non-obviousness of the present invention, applicant would like to add that an unobvious feature of the present invention resides in the ability of a parent to utilize an individualized feeding profile which is based on the needs of the specific infant and which may be altered with the varying needs or the health condition of that particular infant.

Whereas the mother has the ability to modulate the calories consumed by the infant, by changing the order of the

breast milk, i.e. starting with the hind or the fore milk and correspondingly get more or less fat in the complete meal, with general formula feeding such a modulating possibility does not exist. Hitherto, all infants throughout the world are fed by the same composition: which is the idea behind the "one globe one formula!" homogenic paradigm. This generic composition which has a mid-way fat content between fore milk and hind milk fat concentrations is clearly different from the highly variable composition of mother's milk.

This homogenic paradigm, namely the use of one general formula for all babies irrespective of such parameters as health issues and weight, is the art recognized standard which is still maintained as the feeding method of choice, despite the fact that infants who are bottle-fed are more prone to overweight. Applicant's method flies in the face of the prior art standard. Such modulation of the feeding according to the present invention would provide additional tools for controlling the food intake and thus the weight gain that is known to be critical even at this age.

Another way of looking at the benefit of such a method as that of the present invention, which may not be said to result from the Woolridge study, is that starting with a fast-breaking pre-meal liquid such as soup, as is the practice

of individuals on sliming diet, allows stomach satiety earlier in the meal which brings about the need for larger volumes of high fat foods. It is accepted that the stomach satiety is *volume dependent* and intestinal satiety is *nutritional dependent*. Thus, feeding the infant firstly for stomach satiety and self preparation for digestion of the coming fat (induction of gastric lipase) seems quite important to be simulated by a formula feeding such as the one of the present invention. Infant who suffer badly from Colic, may do better starting with hind milk equivalent, which relaxes the stomach and not with fore milk with a low fat content which aggravates the condition.

As stated above, by the method of the present invention, the parent has the option of planning and deciding the amount of low-fat or high-fat milk formula that the infant will be fed, thereby controlling the amounts of calories that the infant ingests. Typically, with the standard one-formula model, controlling or reducing the amounts of calories would not be possible unless the parent dilutes the formula. However, such a dilution action has the disadvantage of also reducing the amounts of nutritional elements essential to normal growth and development.

Accordingly, claim 1 defines non-obvious subject matter from Woolridge either alone or in any possible combination with the other four citations. New claim 16 contains the same subject matter and thus is patentable for the same reasons. All the other claims depend from and incorporate the subject matter of claim 1, and thus are patentable for the same reasons. Accordingly, withdrawal of the rejection is in order and is respectfully requested.

Claim 7 has been rejected as obvious under Section 103 from the same five-reference combination applied above, further in view of Simmons, for reasons set forth in the preceding Office Action. However, the preceding Office Action at the bottom of page 4 refers to Vinciguerra, not Simmons. Applicant accordingly requests clarification.

Regardless, claim 7 depends from and incorporates the subject matter of claim 1, and is therefore patentable for the same reasons as set forth above, regardless of the obviousness of the combination, it being clear that the subsidiary reference in question (Simmons? or Vinciguerra?) does not make up for the aforementioned deficiencies of Woolridge.

Applicant respectfully requests withdrawal of the rejection.

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Applicant respectfully requests favorable
reconsideration, entry of the amendment presented above and
allowance.

Respectfully submitted,
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